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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,684	10/17/2003	Hiroki Fujihira	NANP113US	9339

23623 7590 08/10/2005

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EXAMINER	
CEPERLEY, MARY	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/687,684	FUJIHIRA ET AL.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/20/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

2) The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3) Claims 2 and 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps to specifically describe an "immunoassay of (for?) dioxins" as recited in the preamble of claim 2. An appropriate sequence of method steps would include a step in which specific binding between the corresponding members of a specific binding pair occurs, a step for the detection of this binding by the use of an appropriate label (tracer?) and a step for the correlation of the detection of binding with the presence/amount of dioxin analyte in the sample. Alternatively, Jepson language may be appropriate ("in an immunoassay for the detection of dioxins...wherein the improvement comprises..."). Further, for claims 2-4, it is unclear what is meant by the term "is used as an antigen" since an "antigen" is typically used to prepare an antibody and is not used as an unlabeled component of an immunoassay (unless it is the analyte *per se*). The claims provide for the use of a compound of formulas (I) or (II) in an immunoassay, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

b) For claim 5, it is unclear how the compound of formula (I) would function as a component of an immunoassay kit. It would appear that this compound is a hapten which is useful to prepare an immunogen which is then used to prepare the corresponding antibody; the relevance of this compound to an "immunoassay kit" is unclear. It is similarly unclear how the compound of formula (II) wherein "Z" is a "carrier compound" (antigenic protein) would function as a component of an "immunoassay kit".

c) Claim 6 is confusing and indefinite for the following reasons:

i) It is unclear what is meant by the term "as an antigen" in the context of an "immunoassay kit".

ii) The relative binding specificities of the "antigen", "primary antibody" and "labeled secondary antibody to the primary antibody" cannot be determined.

iii) It would appear that the compound of formula (II) wherein "Z is a carrier compound" (antigenic protein) would not be a conventional component of an "immunoassay kit".

4) 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5) Claims 2 and 4 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

6) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawada et al (HCAPLUS 1998: 239541 describing JP 10101615).

Kawada et al describe a 2,4,5-trichlorophenoxyalkyl carboxylic acid and its conjugates with BSA and KLH which anticipate the compounds (haptens and immunogens) of instant claims 1 and 3 wherein n = 1. See Kawada et al, HCAPLUS printout, page 61, first structure.

8) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9) Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawada et al (HCAPLUS 1998: 239541 describing JP 10101615).

Kawada et al is applied for its description of compounds as discussed in paragraph ***7)*** above. The packaging of conventional reagents in kit form, as claimed, is an obvious expedient for ease and convenience in assay performance. Note that the "for dioxins" description (for use in) of claim 5 is not a limitation on the "kit" *per se*, i.e. the kit is comprised of the stated components independent of any intended method of use.

10) Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Eremin et al (HCAPLUS 1995: 562387 describing Voprosy Meditsinskoi Khimii (1994) 40(4), 57-60).

Eremin et al describe a 2,4,5-trichlorophenoxyalkyl carboxylic acid and its conjugates with a fluoroscein label anticipate the compounds (haptens and tracers) of instant claims 1 and 3 wherein n = 1. See Eremin et al, HCAPLUS printout, the structure of page 73.

11) Claims 5 and 6 arerejected under 35 U.S.C. 103(a) as being unpatentable over Eremin et al (HCAPLUS 1995: 562387 describing Voprosy Meditsinskoi Khimii (1994) 40(4), 57-60).

Eremin et al is applied for its description of compounds as discussed in paragraph ***10)*** above. The packaging of conventional reagents in kit form, as claimed, is an obvious expedient for ease and convenience in assay performance. Note that the "for dioxins" description (for use in) of claim 5 is not a limitation on the "kit" *per se*, i.e. the kit is comprised of the stated components independent of any intended method of use.

12) Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Rinder et al (HCAPLUS 1981: 401702 describing Bull. Environ. Contam. and Toxicology (1981) 26(3), 375-380).

Rinder et al describe a 2,4,5-trichlorophenoxyalkyl carboxylic acid and its corresponding immunogenic conjugates which anticipate the compounds (haptens and immunogens) of instant claims 1 and 3 wherein n = 1. See the structure of page 86 of the HCAPLUS printout.

13) Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rinder et al (HCAPLUS 1981: 401702 describing Bull. Environ. Contam. and Toxicology (1981) 26(3), 375-380).

Rinder et al is applied for its description of compounds as discussed in paragraph ***12)*** above. The packaging of conventional immunoassay reagents in kit form, as claimed, is an obvious expedient for ease and convenience in assay performance. Note that the "for dioxins" description (for use in) of claim

5 is not a limitation on the "kit" *per se*, i.e. the kit is comprised of the stated components independent of any intended method of use.

14) Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of Fujirebio JP 2002-128731 and JP 2002-131316 (English translations: see IDS of January 20, 2004).

Each of the references describes haptens and immunogens which anticipate the compounds of claims 1 and 3. See JP 131316 (English translation): the acid form of the compound of claim 1 wherein $R^1 - R^3$ = chlorine, m = 5-7 {paragraph [0021]}; the immunogen of claim 8; JP 128731 (English translation): the compound of claim 1 wherein R^4 = H; R^1 - R^3 = chlorine; reference example 4. Although the references do not specifically describe the 2, 4, 5-trichloro isomer of the instant claims, this isomer is included by the generic definitions of the JP patents which anticipate, or at the very least render obvious, the tri-chlorinated compounds of the instant claims. The packaging of conventional immunoassay reagents in kit form, as claimed in claims 5 and 6, is an obvious expedient for ease and convenience in assay performance. Note that the "for dioxins" description (for use in) of claim 5 is not a limitation on the "kit" *per se*, i.e. the kit is comprised of the stated components independent of any intended method of use.

15) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from

either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mary E. Ceperley

August 02, 2005

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641